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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

13

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
08/963,368

Applicant(s)  
Nolan

Examiner  
F. Pierre VanderVegt

Group Art Unit  
1644



☒ Responsive to communication(s) filed on Apr 13, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 16-28 ~~is~~/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 16-28 ~~is~~/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with the Sequence Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

This application is a divisional of application S.N. 08/789,333, which is a divisional of application S.N. 08/589,108, which is a divisional of application S.N. 08/589,911.

Claims 16-28 are currently pending in this application.

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1. **In view of Applicant's remarks filed April 13, 2000, no outstanding rejections are maintained.**

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2. The following grounds of rejection are made in light of references which have recently come to the Examiner's attention. As a result of the new grounds of rejection, this Office Action is made **NON-FINAL**.

### *Specification*

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3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

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The specification discloses a plethora of amino acid sequences on pages 7-16 (each page), 18, 22, 44, 53, 68, 69, 72 and 73, for example, and nucleic acid sequences on page 56, 57-59 (single sequence), 60, 61, 67-69 (each page), 72, and 73, for example. Applicant should scan the remainder of the instant specification for additional occurrences of sequences. Regardless of whether nucleotide and/or amino acid are specifically claimed in the instant application or not, 37 CFR 1.182(c, d and e) put forth a clear requirement for each sequence to be identified by a SEQ ID NO and be represented both in computer readable form (CRF) and on the paper copy corresponding to the CRF. Applicant must provide an initial CRF, initial paper copy and a statement that the content of the CRF and the paper copy are the same and that they contain no new matter. See MPEP 2422.03-2422.04.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16-23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jellis et al (U2 on form PTO-892, newly cited) in view of U.S. Patent No. 5,723,287 to Russell et al (A2 on form PTO-892, newly cited), Druker et al (B2, newly cited) and Kaufman (U, of record).

The Jellis et al reference teaches a phage display library expressing  $1.5 \times 10^8$  unique random 20 amino acid peptides fused to a coat protein. Jellis et al does not teach retroviral libraries. The '287 patent teaches that "[r]etrovirus display packages could be used for applications analogous to those which have been developed for filamentous bacteriophage" (column 16, lines 62-64 in particular). Kaufman teaches that retroviral vectors can transduce genes into a variety of cell types and into a variety of species and can introduce nearly 100% of the host cells. Kaufman further teaches that the DNA intermediate of retroviruses can integrate into the host chromosome, inserting a gene of interest into a host genome (page 494 in particular). Druker et al teaches the use of a retroviral expression library comprising randomized point mutations (page 6860, first paragraph of "DISCUSSION" in particular) in a cDNA coding for polyoma middle T antigen (MTAg). The Druker et al library is biased for "studying the transforming ability of MTA<sub>g</sub>" (Abstract in particular). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to create a peptide library in retroviral vectors. One would have been motivated with a reasonable expectation of success by the desire to create only a single library of vector-borne peptides in order to use the same library both for the screening process and for the stable transformation of mammalian cells for expression of the desired peptides and by the teaching of the '287 patent that retroviral display packages could be used for applications analogous to those of a phage display library.

5. Claims 16-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jellis et al (U2 on form PTO-892, newly cited) in view of U.S. Patent No. 5,723,287 to Russell et al (A2 on form PTO-892, newly cited), Druker et al (B2, newly cited), Kaufman (U. of record), and Nilsson et al (V. of record).

5 The Jellis et al reference, the '287 patent, Kaufman and Druker et al have been discussed supra. The combined references do not teach the expression of the variety of claimed fusion proteins [claims 24-26]. Nilsson et al teaches that fusion proteins are constructed for a variety of purposes, such as increasing the stability of the product [claim 26], both during purification or in vivo use of the product (pages 570-571 in particular). Nilsson et al further teaches that fusion of  
10 a desired protein product with a 'handle' that has unique binding characteristics facilitates purification (rescue) of the desired protein so that the protein which confers a particular phenotype of interest on the host cell can be retrieved for further study [claim 25]. Nilsson et al also teaches that a further reason to construct a fusion protein would be for targeting of protein drugs (page 572 in particular)[claim 24]. It would have been prima facie obvious to a person of  
15 ordinary skill in the art at the time the invention was made to combine the teachings of Nilsson et al with those of the other references. One would have been motivated to combine these teachings with a reasonable expectation of success based on the teachings of Nilsson et al that fusion proteins can be constructed for a variety of reasons ranging from protein recovery to therapeutic uses. Claim 27 is included because dimerization of a recombinant peptide is well known in the art  
20 to be effective for increasing the immunogenicity of antigenically weak peptides which are of interest as potential immunospecific targets to treat a particular condition.


### *Conclusion*

6. The lengthy specification has not been checked to the extent necessary to determine the  
25 presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

7. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
June 23, 2000



F. PIERRE VANDERVEGT  
PATENT EXAMINER